

**IN THE UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE**

NIPPON SHINYAKU CO., LTD., a
Japanese company;

Plaintiff,

v.

SAREPTA THERAPEUTICS, INC., a
Delaware corporation

Defendant.

CIVIL ACTION NO. 1:21-CV-01015-LPS

**PLAINTIFF’S OPPOSITION TO DEFENDANT’S MOTION TO DISMISS CLAIMS II-X
AND TO STRIKE SELECT PARAGRAPHS OF NIPPON SHINYAKU’S COMPLAINT**

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I. INTRODUCTION

Nippon Shinyaku Co., Ltd. (“Nippon Shinyaku”) filed an amended complaint on September 10, 2021 (“Amended Complaint,” D.I. 39). Consequently, Sarepta’s Therapeutics, Inc.’s (“Sarepta”) motion to dismiss Claims II-X (D.I. 32-33) of Nippon Shinyaku’s complaint filed on July 13, 2021 (the “Original Complaint,” D.I. 2) is mooted.

Further, Sarepta’s motion to strike [REDACTED] of the “Original Complaint (D.I. 31, 33) is also mooted. To the extent it is not, [REDACTED] in the Amended Complaint, the motion to strike should be denied. [REDACTED]

[REDACTED] prejudices Sarepta. Sarepta is wrong at least for the following two reasons:

First, Nippon Shinyaku’s [REDACTED] [REDACTED] in its Original and Amended Complaint was proper, including [REDACTED] its declaratory judgment claims (Claims II and III). [REDACTED] [REDACTED]. *See* D.I. 2, [REDACTED] [REDACTED]. The present action includes [REDACTED] [REDACTED] (Claim I), as well as claims for declaratory judgment of non-infringement and invalidity of Sarepta’s UWA Patents (Claims II and III), and claims directed at Sarepta’s infringement of the NS Patents (Claims IV-X). Nippon Shinyaku brought the present action to [REDACTED] [REDACTED] District of Delaware, including its declaratory judgment claims. Nippon Shinyaku’s [REDACTED] [REDACTED] [REDACTED] is thus expressly permissible. Because [REDACTED] there is no basis for striking the disputed paragraphs in the Original or Amended Complaint.

Second, even if Nippon Shinyaku's [REDACTED] [REDACTED] [REDACTED] which it is not, Sarepta still cannot demonstrate any prejudice. Sarepta does not dispute [REDACTED] [REDACTED] and is central to the nucleus of facts around which this dispute arises. Further, there are additional factual allegations in Nippon Shinyaku's First Amended Complaint filed on September 10, 2021 (the "Amended Complaint"), [REDACTED] [REDACTED], which alone are sufficient to establish declaratory judgment jurisdiction. They provide additional and sufficient factual support [REDACTED] to evidence the allegations made in the disputed paragraphs, precluding any finding of prejudice to Sarepta. Accordingly, Sarepta's motion to strike should be denied.

II. NATURE AND STAGE OF PROCEEDINGS

Nippon Shinyaku filed its Original Complaint against Sarepta on July 13, 2021, asserting a [REDACTED]; claims for declaratory judgment of non-infringement and invalidity of Sarepta's UWA Patents¹ (Claims II-III); and claims for Sarepta's infringement of the NS Patents² (Claims IV-X). D.I. 2. Concurrently with its filing of the Original Complaint, Nippon Shinyaku also moved for a preliminary injunction concerning Sarepta's [REDACTED] [REDACTED] Sarepta's filing of seven *inter partes* review ("IPR") petitions. D.I. 4-5. Nippon Shinyaku's motion for preliminary injunction is now fully briefed. *See* D.I. 13, 14, 18, and 25. Sarepta has not sought to strike any portion of or to dismiss Claim I upon which the preliminary injunction is based.

On September 3, 2021, Sarepta filed a Motion to Strike and to Dismiss Claims II-X of Nippon Shinyaku's Complaint (the "Motion"). D.I. 32, 33. Sarepta moved to dismiss Claims II-III for lack of declaratory judgment jurisdiction; Claim II under Rule 12(b)(6) for failing to state a

¹ The UWA Patents are defined in Nippon Shinyaku's Original Complaint. D.I. 2 at ¶ 2.

² The NS Patents are defined in Nippon Shinyaku's Original Complaint. D.I. 2 at ¶ 3.

claim of non-infringement; and Claims IV-X under Rule 12(b)(7) for failure to join the National Center of Neurology and Psychiatry (“NCNP”) as a necessary party pursuant to Rule 19. D.I. 33. Sarepta’s arguments for dismissal of Claims II and III for lack of declaratory judgment jurisdiction were premised on the Court striking [REDACTED] of the Original Complaint, which provided factual support for this Court’s declaratory judgment jurisdiction over those claims. *Id.* at 12.

Nippon Shinyaku filed its First Amended Complaint on September 10, 2021 pursuant to Federal Rule of Civil Procedure 15. The Amended Complaint also [REDACTED] [REDACTED] included in the Original Complaint as [REDACTED] (collectively, the “Disputed Paragraphs”). *Compare* D.I. 39 at [REDACTED] and D.I. 2 at [REDACTED]. Again, not conceding any of the arguments made in the motion to strike, the Amended Complaint includes additional facts and allegations supporting its claims for declaratory judgment of non-infringement and invalidity of Sarepta’s UWA Patents in Claims II and III as well as additional facts regarding [REDACTED] Nippon Shinyaku and NCNP relating to Claims IV-X. *See, e.g.*, D.I. 39 at ¶¶ 13-21, 47-49, 79-89, 92-101; D.I. 39-5.

III. SAREPTA’S MOTION TO DISMISS CLAIMS II-X SHOULD BE DENIED AS MOOT

Sarepta’s motion to dismiss Claims II-X of the Original Complaint should be dismissed as moot given Nippon Shinyaku’s filing of an Amended Complaint, as “an amended complaint supersedes the original complaint” and “renders it of no legal effect, unless the amended complaint specifically refers to or adopts the earlier pleading.” *See, e.g., W. Run Student Hous. Assocs., LLC v. Huntington Nat’l Bank*, 712 F.3d 165, 171 (3d Cir. 2013); *see also Pac. Bell Tel. Co. v. linkLine Commc’ns, Inc.*, 555 U.S. 438 (2009).

In its Motion, Sarepta moved to dismiss Claims II-III under Rule 12(b)(1) for lack of subject matter jurisdiction of the declaratory judgment claims. D.I. 33 at 12-13. Without conceding the merits of any of Sarepta's arguments in its motion to dismiss, its arguments on these claims, are now moot given that Nippon Shinyaku plead additional facts in support of declaratory judgment jurisdiction in its Amended Complaint. D.I. 39 at ¶¶ 12-21, 79-88, 92-101.

Sarepta also moved to dismiss Claim II under Rule 12(b)(6) for failure to state a claim of non-infringement. D.I. 33 at 13-16. Sarepta's arguments on these claims are likewise moot given the additional facts plead. D.I. 39 at ¶ 89.

Finally, Sarepta's motion to dismiss Claims IV-X under Rule 12(b)(7) for failure to join NCNP as a party to the litigation should also be denied as moot given additional facts plead by Nippon Shinyaku in its Amended Complaint. D.I. 33 at ¶¶ 47-49; D.I. 39-5.

IV. SAREPTA'S MOTION TO STRIKE UNDER RULE 12(F) SHOULD BE DENIED

"As a general matter, motions to strike under Rule 12(f) are disfavored." *Vite Techs., LLC v. Smith & Nephew, Inc.*, No. 14-1507-SLR, 2015 WL 4486785, at *2 (D. Del. July 23, 2015). Sarepta's Motion seeks to strike the Disputed Paragraphs [REDACTED] of the Original Complaint that state:

There is an actual case and controversy between Nippon Shinyaku and Sarepta regarding the UWA Patents that confers jurisdiction to this Court under 28 U.S.C. § 2201, as evidenced by Sarepta's [REDACTED]

[REDACTED] This actual case and controversy is also evidenced by Sarepta's [REDACTED]

D.I. 2 [REDACTED]

A. [REDACTED]

Sarepta asserts that [REDACTED]

[REDACTED] of the Complaint should be stricken in their entirety under Rule 12(f) as ‘impertinent’ and ‘immaterial.’” D.I. 33 at 8. Sarepta’s argument is based solely on [REDACTED]

[REDACTED] See D.I. 33 at 4, 8-10.

This [REDACTED], however, is not dispositive. [REDACTED]

[REDACTED]” D.I. 2, [REDACTED] Sarepta concedes that this [REDACTED]

[REDACTED] but wrongly argues that this [REDACTED]

[REDACTED] D.I. 33

at 10-11.

Here, it is undisputed that Nippon Shinyaku [REDACTED]

[REDACTED] (Motion, D.I. 33 at 10), which [REDACTED]

[REDACTED] D.I. 2,

[REDACTED] Because this is an action [REDACTED]

[REDACTED]. Thus, there is no basis for this Court to find that the Disputed Paragraphs are “impertinent” and “immaterial” or to strike them from the Original or Amended Complaint.

Sarepta's attempts to distinguish Nippon Shinyaku's reliance on the Disputed Paragraphs from [REDACTED]. Sarepta contends, without support, that [REDACTED]. D.I. 33 at 9-10. However, nothing [REDACTED]. Rather, [REDACTED]. D.I. 2, [REDACTED]. This is one such [REDACTED]. Accordingly, this Court should deny Sarepta's motion to strike these paragraphs.

B. Sarepta is not prejudiced by the Disputed Paragraphs.

Even assuming, *arguendo*, that the [REDACTED], this alone would not justify striking them. As courts in this district have found, "even where the challenged material is redundant, immaterial, impertinent, or scandalous, a motion to strike should not be granted unless the presence of the surplusage will prejudice the adverse party." *Symbol Techs., Inc. v. Aruba Networks, Inc.*, 609 F. Supp. 2d 353, 359 (D. Del. 2009).

Sarepta does not dispute, and necessarily concedes, that [REDACTED] in the Disputed Paragraphs is properly pled to [REDACTED], which are central to the factual nucleus from which this dispute and action arise. *See* D.I. 33 at 10-11. Because the Disputed Paragraphs are properly pled within the scope of the Original Complaint, Sarepta cannot establish prejudice from those same facts appearing in the Disputed Paragraphs.

Sarepta also cannot demonstrate any prejudice arising from the inclusion of the Disputed Paragraphs because they are supported [REDACTED] as is made clear by the additional factual allegations in the Amended Complaint. Contrary to Sarepta's assertion, there

are [REDACTED] that also [REDACTED] in the Disputed Paragraphs. As detailed in Nippon Shinyaku's Amended Complaint, such [REDACTED]

[REDACTED].
For example, [REDACTED] [REDACTED]. D.I. 39 at ¶ 16. As a result of [REDACTED] [REDACTED] [REDACTED]. *Id.*

[REDACTED] *Id.*
Additionally, during that same timeframe and before [REDACTED] [REDACTED] [REDACTED]. *Id.* at ¶ 17. [REDACTED] [REDACTED]. *Id.*

Further, on [REDACTED] [REDACTED] [REDACTED] D.I. 39 at ¶ 19. [REDACTED] [REDACTED] D.I. 39-4 (emphasis added). Then, on [REDACTED], Nippon Shinyaku [REDACTED] [REDACTED]. D.I. 39 at ¶ 21. Sarepta [REDACTED]. *Id.*

These facts and circumstance (*see* D.I. 39 ¶¶ 11-21), including Sarepta's [REDACTED]

provide ample basis for declaratory jurisdiction. *See MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007).

SanDisk Corp. v. STMicroelectronics, Inc., 480 F. 3d 1372, 1375 n. 1 (Fed. Cir. 2007),

In *SanDisk*,

Id. Here, as discussed above, the

████████████████████. Nippon Shinyaku also included in the Amended Complaint additional ██████████ facts supporting ██████████. For these reasons, ██████████ ██████████ in *SanDisk* is inapplicable.³

Because the statements in the Disputed Paragraphs are indisputably properly pled within the scope of the claims in Original and Amended Complaints and because additional facts not [REDACTED] plead in Nippon Shinyaku's Amended Complaint also support [REDACTED] made in the Disputed Paragraphs, there can be no prejudice to Sarepta in including them in the Amended Complaint. Accordingly, Sarepta's motion to strike under Rule 12(f) should be denied.

³ The remaining two cases on which Sarepta relies—*Victor G. Reiling Assocs. & Design Innovation, Inc. v. Fisher-Price, Inc.*, 407 F. Supp. 2d 401, 404 (D. Conn. 2006) and *Osteotech, Inc. v. Regeneration Techs., Inc.*, No. 3:06-cv-04249-FLW, 2008 WL 4449564, at *4 (D.N.J. Sept. 25, 2008) are inapplicable for the same reason as *SanDisk*. See D.I. 33 at 9-10. [REDACTED]

G. Reiling Assocs., 407 F. Supp. 2d at 404 and *Osteotech*, 2008 WL 4449564, at *4. Victor

V. CONCLUSION

This Court should deny as moot Sarepta's motion to dismiss Claims II-X, and to the extent not moot, deny Sarepta's motion to strike under Rule 12(f).

Dated: September 17, 2021

Respectfully submitted,

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